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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/797,606 | 03/11/2004 | Masato Kurokawa | 042190 | 3867 |

38834 7590 10/20/2006

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| EXAMINER |
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GUDIBANDE, SATYANARAYAN R

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,606

Applicant(s)

KUROKAWA ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/20/06 has been entered.

Claims 1-3 have been amended and claim 9 has been added as a new claim.

Claims 1-9 are pending.

Claim 8 has been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-7 and 9 have been examined on merit.

Withdrawn Rejection

Claim Rejections - 35 USC § 103

Applicant's arguments see pages 4-8 and the declaration under Rule 132, filed 9/20/06, with respect to Claim Rejections - 35 USC § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,184,348 B1 issued to Ferrari, et al., in view of US 5,916,585 issued to Cook, et al.

In the instant application, applicants claim a wound dressing for accelerating epidermal regeneration which **comprises**, RGD and GAGAGS peptides, a polyalkylenepolyamine having a molecular weight of 2000 to 60,000 d, and a sheet (s) being at least one member selected from the group consisting of polyolefin, polyurethane, polyester, polyamide, polystyrene and silicone resin.

Ferrari, et al., discloses the composition of the peptide copolymer of RGD and GAGAGS peptides in claims 4-6 of US 6,184,348 B1 (column 141, lines 8-29). The reference also teaches that the aforementioned copolymers can be deposited onto other substrates and materials for a

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cell-binding surface. Such coated materials or substrates are used for wound dressing that promotes enhanced healing (Column 28, lines 35-45). The reference of Ferrari, does not teach the use of polyalkylenepolyamine or polyarylenepolyamine matrices.

Cook, et al discloses materials and methods for the immobilization of bioactive species onto biodegradable polymers. The invention is directed to hydrophobic degradable polymeric material having at least one surface thereof rendered hydrophilic by cross-linking a hydrophilic polymer layer. The bioactive species are either reversibly immobilized or cross-linked with the cross linking agent that cross-links the hydrophilic polymer with the hydrophobic biodegradable polymeric material (abstract). Cook, et al., discloses suitable polymeric material that forms the biodegradable hydrophobic surface as polyesters of oxalic acid and polyurethanes (bridging paragraph of columns 9 and 10 and claim 4) which is the sheet (s) of the instant application. This meets the limitations of claim 1 and 9. The biodegradable hydrophilic surfactant layer comprises of polyethyleneimine and other polyalkylenepolyamines (claim 7, 25 and 30), meeting the limitations of claims 1 and 7. The reference also discloses the variety of bioactive species immobilized on the biodegradable polymeric material that includes tripeptide Arg-Gly-Asp (column 6, line 60) meeting the limitations of claim 1. Example 18 of the reference uses the polymeric material of the invention for a surgical mesh made up of PGA:PLA fiber mesh and an antimicrobial drug gentamycin reversibly cross-linked to polyethyleneimine (PEI) to treat surgical wounds to prevent infection (column 21, example 18).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Ferrari and Cook to design a wound dressing for accelerated epidermal regeneration. Ferrari, teaches the composition of the peptides ARG and GAGAGS that can be used as a coating on

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materials or substrates used for wound dressing. Cook describes the material and methods for immobilization of bioactive species onto biodegradable polymers. The motivation to combine teachings of Ferrari and Cook was available in Ferrari as the reference teaches that the peptide composition may be coated on a matrix of woven fabric or film or membrane and used as wound dressing to promote enhanced healing due to attachment of cells involved in the healing and Cook describes such a method to immobilize bioactive materials onto biodegradable polymeric matrix. There would have been reasonable expectation of success in the present instance to combine the teachings of Ferrari and Cook to design a wound dressing composition for rapid epidermal regeneration because such a method and use of polymeric matrix has been disclosed by the references. Ferrari teaches the peptides that can be used as bioactive ingredients Cook teaches the polymeric matrix composed of polyurethane sheet with hydrophilic layer of polyethyleneimine for the adsorption or cross-linking of the bioactive peptides to form the wound dressing. Cook also successfully teaches a surgical mesh made up of PGA:PLA fiber mesh and an antimicrobial drug gentamycin reversibly cross-linked to polyethyleneimine (PEI) to treat surgical wounds to prevent infection. Therefore, the invention as a whole is clearly a prima-facie obvious to one skilled in the art at the time the invention was made to combine the teachings of Ferrari and Cook to formulate a wound dressing composition.

Claim Objections

Claims 1, 5 and 6 are objected to because of the following informalities: The claims contain amino acid sequences that require identifying SEQ ID NOs. The amino acid sequences are to be represented properly for example, Arg-Gly-Asp (SEQ ID NO: ?) with amino acid

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notations properly **connected to each other** to represent a peptide sequence properly.

Appropriate correction is required.

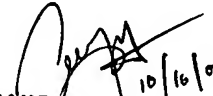
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
SENIOR EXAMINER

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654